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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,291	09/11/2003	Robert Markes	1339BGN-US	5615

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Dekel Patent Ltd.
Beit HaRofim
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EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/659,291

Applicant(s)

MARKES, ROBERT

Examiner

Lyle A. Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is not clear what type of destructive fluids to neutralize the sample are intended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2,4-7,9-11 and 13-14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shain et al. (USP 6,027,349) or Douglas et al. (USP 5,951,492).

Both of these references teach a sampling instrument having a first and second housing, reagents suitable for glucose testing and an optical sensor that displays the blood glucose level. Both of these devices teach means to pump the fluid. With respect to the limitations directed to being disposable and reusable, the maintains both cited references have this capability.

Claims 1-2,4-7 and 9-14 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Moerman et al. (USP 6,706,159) or Stiene et al. (2004/0096959).

Moerman et al. teach a sampling instrument having a first and second housing, reagents suitable for glucose testing and an optical sensor that displays the blood glucose level. Figure 2 teaches the retractable needle. Figure (8G) teaches pump(806). Column 9 lines 35-56 teach the wireless transmission. With respect to the limitations directed to being disposable and reusable, the maintains both cited references have this capability.

Stiene et al. teach a glucose sensor comprising a microneedle(4), electro-osmotic pump(10), microchannel(8) and electrochemical detector(11). Paragraph [0107] teaches a waste reservoir in figure 17(b). Paragraph [081] teaches the device is "disposable". Paragraph [044] teaches the pumping can be either mechanical or electro-osmotic. Paragraph [033] teaches the sensing means. Paragraph [0118] teaches wireless technology.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shain et al. (USP 6,027,349), Douglas et al. (USP 5,951,492), Moerman et al. (USP 6,706,159) or Stiene et al. (2004/0096959).

See Shain et al. (USP 6,027,349), Douglas et al. (USP 5,951,492), Moerman et al. (USP 6,706,159) and Stiene et al. (2004/0096959) supra.

The cited prior art is silent to the claimed "destructive fluids for neutralizing substances".

It is well known in the art that blood is a biohazard and contact with blood should be avoided. It is also well known in the art that biohazard materials can be neutralized of most pathogens by inexpensive disinfectants. It is desirable to neutralize pathogens in blood sample to minimize the chance of infection by the technician or person(s) responsible for the disposal of blood samples. It would have been within the skill of the

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art to modify Shain et al. (USP 6,027,349), Douglas et al. (USP 5,951,492), Moerman et al. (USP 6,706,159) or Stiene et al. (2004/0096959) and incorporate a disinfectant to neutralize the previously analyzed blood sample to gain the above advantages.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shain et al. (USP 6,027,349), Douglas et al. (USP 5,951,492), Moerman et al. (USP 6,706,159) or Stiene et al. (2004/0096959) in view of Eason et al (USP 5,186,897).

See Shain et al. (USP 6,027,349), Douglas et al. (USP 5,951,492), Moerman et al. (USP 6,706,159) and Stiene et al. (2004/0096959) supra.

These references are silent to use of an optical waveguide.

Eason et al. teach in columns 2-3 lines 15-7 respectively teach optical waveguides are advantageous because they eliminate the need to separate and wash the sample.

It would have been within the skill of the art to modify Shain et al. (USP 6,027,349), Douglas et al. (USP 5,951,492), Moerman et al. (USP 6,706,159) or Stiene et al. (2004/0096959) in view of Eason et al. and use an optical waveguide to gain the above advantages.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander
Primary Examiner
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